

244

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 6B4516) has been filed by Zeneca Inc., Foulkstone 1405, 2d, 1800 Concord Pike, Wilmington, DE 19850-5457. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of 2-methyl-4,5-trimethylene-4-isothiazolin-3-one as a preservative for paper and paperboard coatings used in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before September 26, 1996, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: August 8, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.
[FR Doc. 96-21845 Filed 8-26-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96E-0099]

Determination of Regulatory Review Period for Purposes of Patent Extension; CEDAX® Oral Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CEDAX® Oral Suspension and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product. **ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was

issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product CEDAX® Oral Suspension (ceftibuten dihydrate). CEDAX® Oral Suspension is indicated for the treatment of individuals with mild-to-moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions: Acute Bacterial Exacerbations of Chronic Bronchitis due to *Haemophilus influenzae* (including B-lactamase-producing strains), *Moraxella catarrhalis* (including B-lactamase producing strains) or *Streptococcus pneumoniae* (penicillin-susceptible strains only), Acute Bacterial Otitis Media due to *Haemophilus influenzae* (including B-lactamase producing strains), *Moraxella catarrhalis* (including B-lactamase producing strains) or *Streptococcus pyogenes*, or Pharyngitis and Tonsillitis due to *Streptococcus pyogenes*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CEDAX® Oral Suspension (U.S. Patent No. 4,634,697) from Schering-Plough Corp. and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 10, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CEDAX® Oral Suspension represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CEDAX® Oral Suspension is 2,641 days. Of this time, 1,179 days occurred during the testing phase of the regulatory review period, while 1,462 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective: September 28, 1988.* The applicant claims September 29, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 28, 1988, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357):* December 20, 1991. FDA has verified the applicant's claim that the new drug application (NDA) for CEDAX® Oral Suspension (NDA 50-686) was initially submitted on December 20, 1991.

3. *The date the application was approved:* December 20, 1995. FDA has verified the applicant's claim that NDA 50-686 was approved on December 20, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 28, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 24, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 16, 1996.
Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
[FR Doc. 96-21844 Filed 8-26-96; 8:45 am]
BILLING CODE 4160-01-F

[Docket No. 96E-0153]

Determination of Regulatory Review Period for Purposes of Patent Extension; ARIMIDEX®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ARIMIDEX® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ARIMIDEX®

(anastrozole). ARIMIDEX® is indicated for the treatment of advanced breast cancer in postmenopausal women with disease progression following tamoxifen therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ARIMIDEX® (U.S. Patent No. 4,935,437) from Zeneca Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 28, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ARIMIDEX® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ARIMIDEX® is 1,336 days. Of this time, 1,062 days occurred during the testing phase of the regulatory review period, while 274 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* May 2, 1992. The applicant claims May 1, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 2, 1992, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* March 29, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for ARIMIDEX® (NDA 20-541) was initially submitted on March 29, 1995.

3. *The date the application was approved:* December 27, 1995. FDA has verified the applicant's claim that NDA 20-541 was approved on December 27, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 565 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 26, 1996, submit